General

Guideline Title

American Academy of Orthopaedic Surgeons clinical practice guideline on the treatment of pediatric diaphyseal femur fractures.

Bibliographic Source(s)

American Academy of Orthopaedic Surgeons (AAOS). American Academy of Orthopaedic Surgeons clinical practice guideline on treatment of pediatric diaphyseal femur fractures. Rosemont (IL): American Academy of Orthopaedic Surgeons (AAOS); 2015 Jun 12. 102 p. [50 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: American Academy of Orthopaedic Surgeons (AAOS). American Academy of Orthopaedic Surgeons clinical practice guideline on treatment of pediatric diaphyseal femur fractures. Rosemont (IL): American Academy of Orthopaedic Surgeons (AAOS); 2009 Jun 19. 110 p. [49 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Definitions of the strength of recommendation (Strong, Moderate, Limited, Consensus) and strength visual (****, ***, **, *) are provided at the end of the "Major Recommendations" field.

Note from the American Academy of Orthopaedic Surgeons (AAOS): The following is a summary of the recommendations in the AAOS' clinical practice guideline on the Treatment of Pediatric Diaphyseal Femur Fractures. This summary does not contain rationales that explain how and why these recommendations were developed nor does it contain the evidence supporting these recommendations. All readers of this summary are strongly urged to consult the full guideline and evidence report for this information. The authors are confident that those who read the full guideline and evidence report will also see that the recommendations were developed using systematic evidence-based processes designed to combat bias, enhance transparency, and promote reproducibility. This summary of recommendations is not intended to stand alone.

Summary of Recommendations

Child Abuse

Strong evidence supports that children younger than thirty-six months with a diaphyseal femur fracture be evaluated for child abuse. Grade of Recommendation: Strong ****

Infant Femur Fracture

Limited evidence supports treatment with a Pavlik harness or a spica cast for infants six months and younger with a diaphyseal femur fracture, because their outcomes are similar. Grade of Recommendation: Limited **

Early or Delayed Spica Casting

Moderate evidence supports early spica casting or traction with delayed spica casting for children age six months to five years with a diaphyseal femur fracture with less than 2cm of shortening. Grade of Recommendation: Moderate ***

Elastic Intramedullary Nails

Limited evidence supports the option for physicians to use flexible intramedullary nailing to treat children age five to eleven years diagnosed with diaphyseal femur fractures. Grade of Recommendation: Limited **

Open Reduction and Internal Fixation (ORIF) Pediatric Femur Fractures

Limited evidence supports rigid trochanteric entry nailing, submuscular plating, and flexible intramedullary nailing as treatment options for children age eleven years to skeletal maturity diagnosed with diaphyseal femur fractures, but piriformis or near piriformis entry rigid nailing are not treatment options. Grade of Recommendation: Limited **

Pain Control

Limited evidence supports regional pain management for patient comfort perioperatively. Grade of Recommendation: Limited **

Waterproof Casting

Limited evidence supports waterproof cast liners for spica casts are an option for use in children diagnosed with pediatric diaphyseal femur fractures. Grade of Recommendation: Limited **

Definitions

Strength of Recommendation Descriptions

Strength	Overall Strength of Evidence	Description of Evidence Strength	Strength Visual
Strong	Strong	Evidence from two or more "High" strength studies with consistent findings for recommending for or against the intervention.	****
Moderate	Moderate	Evidence from two or more "Moderate" strength studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.	***
Limited	Low Strength Evidence or Conflicting Evidence	Evidence from two or more "Low" strength studies with consistent findings or evidence from a single study for recommending for or against the intervention or diagnostic test or the evidence is insufficient or conflicting and does not allow a recommendation for or against the intervention.	**
Consensus	No Evidence	There is no supporting evidence. In the absence of reliable evidence, the work group is making a recommendation based on their clinical opinion. Consensus recommendations can only be created when not establishing a recommendation could have catastrophic consequences.	*

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Disease/Condition(s)

Diaphyseal femur fracture

Guideline Category

Management

Treatment

Clinical Specialty

Emergency Medicine

Orthopedic Surgery

Pediatrics

Intended Users

Advanced Practice Nurses

Health Care Providers

Hospitals

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To help improve the treatment of pediatric diaphyseal femur fractures in pediatric patients based on the current best evidence

Target Population

Children who have not yet reached skeletal maturity with isolated diaphyseal fractures

Note: This guideline is not intended for use in pediatric patients who present with additional coexisting injuries that require formal surgical intervention or other life-threatening conditions that take precedence over the treatment of the diaphyseal femur fracture.

Interventions and Practices Considered

1. Evaluation for child abuse
2. Pavlik harness or spica cast (including waterproof cast liners) as age appropriate
3. Flexible intramedullary nailing as age appropriate
4. Rigid trochanteric entry nailing, submuscular plating, and flexible intramedullary nailing as age appropriate
5. Pain management

Major Outcomes Considered

- Incidence of fractures caused by child abuse
- Length of hospital stay

- Cost
- Mobility
- Complications (angulation, infection, malunion, etc.)
- Duration of treatment/return to school
- Patient satisfaction

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

2015 Guideline Reissue

The original guideline and systematic review (see the "Availability of Companion Documents" field) were prepared by the American Academy of Orthopaedic Surgeons (AAOS) Pediatric Diaphyseal Femur Fractures physician work group with the assistance of the AAOS Clinical Practice Guidelines Unit. Based on the current procedure for updating AAOS guidelines, the Medical Librarian ran an updated search to identify literature published after the original search for the 2009 guideline that could address and possibly change the original recommendations. The AAOS Evidence Based Medicine Unit then used the inclusion criteria from the original guideline to determine if any articles published after the final literature search date of the original guideline were relevant to the recommendations.

Study Selection Criteria: Types of Studies

A priori article selection criteria were developed for the review. Specifically, to be included in the systematic reviews an article had to be a report of a study that:

- Evaluated a treatment for isolated pediatric diaphyseal femur fracture
- Was a full article published in the peer reviewed literature
- Was an English language article published after 1965
- Was not a cadaveric, animal, or *in vitro* study
- Was not a retrospective case series, medical records review, meeting abstract, unpublished study report, case report, historical article, editorial, letter, or commentary
- Was the most recent report of a study or the report with the largest number of enrolled patients in a study with multiple publications
- Enrolled ≥10 patients in each of its study groups
- Enrolled a patient population of at least 80% of patients with a diaphyseal femur fracture and were not skeletally mature (closure of proximal and distal femoral growth plates)
- Reported quantified results
- Enrolled patients without the following conditions
    - Subtrochanteric fractures, supracondylar femur fractures, physeal fractures, open fractures, compound fractures, pathologic fractures, or multiple lower extremity fractures
    - Co-existing abdominal or neurological injuries requiring surgical intervention (the physician work group chair and co-chair determined whether an article met inclusion criteria in cases when studies reported insufficient detail to determine whether co-existing injuries required surgical intervention)
    - Osteogenesis imperfecta, cerebral palsy, myelodysplasia (spina bifida), metabolic bone diseases, or skeletal dysplasia

When examining primary studies, the guideline work group analyzed the best available evidence regardless of study design. The work group first considered the randomized controlled trials (RCTs) identified by the search strategy. In the absence of two or more RCTs, they sequentially searched for prospective controlled trials, prospective comparative studies, retrospective comparative studies, and prospective case-series studies.

Only studies of the highest level of available evidence were included, assuming that there were 2 or more studies of that higher level. For example, if there were two high quality studies that addressed the recommendation, moderate, low, and very low quality studies were not included.

For the recommendation on waterproof cast liners only, the work group considered for inclusion studies that included patients with conditions other than diaphyseal femur fractures because the complications potentially avoided by using waterproof liners are not specific to diaphyseal femur fractures.

The Pediatric Diaphyseal Femur Fracture physician work group requested that the AAOS guidelines unit capture surrogate outcome measures if the study inclusion criteria were met. For this patient population, children, surrogate outcomes are often used because patients' communication skills are limited or not yet developed. Surrogate outcome measures are laboratory measurements or another physical sign that are used as substitutes for clinically meaningful end points that measure directly how a patient feels, functions, or survives. In order for a surrogate measure to be valid, it must be in the causal pathway between the intervention and the outcome and it must demonstrate a large, consistently measurable association with the outcome.

The main surrogate measures considered were radiographic measures, such as those indicating a malunion of the fracture. It should be noted that generally accepted definitions of malunion have not necessarily been correlated to function and risk of developing further problems.

An outcome was considered only if ≥50% (80% for case series) of the patients were followed for that outcome (for example, some studies reported short-term outcomes data on nearly all enrolled patients, and reported longer-term data on only a few patients. In such cases, the work group did not include the longer-term data). Outcomes were also excluded for study groups that did not have at least 10 patients.

When distinguishing between stable and unstable fractures, the work group defined transverse and short oblique fractures as stable. Comminuted and long oblique fractures were defined as unstable.

When the age range of patients in a study overlapped the target age range of two or more recommendations, the study was included in the evidence base of the recommendation whose age range included the study's median patient age.

Original and Updated Literature Searches

The updated guideline searched for articles published up to November 27, 2013. The original guideline searched for articles published up to October 1, 2008. Search strategies were reviewed by the original work group prior to conducting the searches. All literature searches were supplemented with manual screening of bibliographies of all publications retrieved. The bibliographies of recent systematic reviews and other review articles were also searched for potentially relevant citations. A list of potentially relevant studies, not identified by the literature search, was also provided by the work group members. Three such studies met the inclusion criteria. One recommendation-specific search for primary articles on waterproof cast liners was conducted. For the entire guideline, thirty-two primary studies were included and two hundred forty-three studies were excluded.

Search for RCTs and Other Study Designs

To identify primary studies for this guideline, the work group searched four electronic databases; PubMed, EMBASE, CINAHL, and The Cochrane Central Register of Controlled Trials. The search strategies used are provided in Appendix II in the 2015 guideline reissue. The work group used a previously published search strategy to identify relevant RCTs. In the absence of relevant RCTs, the work group modified the search strategy to identify studies of other designs. The study attrition diagram in Appendix I in the 2015 guideline reissue provides details about the inclusion and exclusion of these studies.

Number of Source Documents

The original search conducted in 2008 (after removal of duplicates) yielded 1181 articles, of which 274 were retrieved and evaluated. The updated search conducted in November 2013 yielded an additional 384 articles published after the original search. The updated search did not yield any new studies that were relevant to the recommendations.

For the entire guideline, 32 primary studies were included and 243 studies were excluded. See Appendix III in the 2015 guideline reissue for attrition flowcharts for the original and updated literature searches.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

The strength of evidence for individual studies was classified as "high," "moderate," or "low" in accordance with the Grading of Recommendations Assessment, Development and Evaluation (GRADE) evidence appraisal system. This system addresses specific quality domains, and each outcome reported is evaluated for flaws within these domains.

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Data Extraction

Data elements extracted from studies were defined in consultation with the physician work group. Three reviewers completed data extraction independently for all studies. Disagreements were resolved by consensus and by consulting the work group. Evidence tables were constructed to summarize the best evidence pertaining to each preliminary recommendation. The elements extracted are shown in Appendix IV in the 2015 guideline reissue.

Statistical Methods

The group calculated, where applicable, odds ratios (OR) for dichotomous data and mean differences for continuous data.

When published studies only reported the median, range and size of the trial, the work group estimated their means and variances according to a published method.

The work group used StatXact for the calculation of exact odds ratios confidence intervals for dichotomous data. All other calculations were performed using STATA 10.0 (StataCorp LP, College Station, Texas). The Wilson score method was used to calculate confidence intervals for proportions. For ordinal data, the work group used ordinal logistic regression to calculate odds ratios. Ordinal logistic regression produces proportional odds ratios, which assumes that the odds ratio is the same between each pair of outcome groups (lowest category vs. all higher categories, lowest two categories vs. all higher categories, etc.).

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

To develop the original 2009 guideline (see the "Availability of Companion Documents" field), the work group initially met in an introductory meeting on April 5, 2008, to establish the scope of the guideline and systematic review. Upon completion of the systematic review the work group participated in a two-day recommendation meeting on November 8 and 9, 2008, at which the final recommendations were written and voted on. The resulting draft guidelines were then peer-reviewed, subsequently sent for public commentary, and then sequentially approved by the American Academy of Orthopaedic Surgeons (AAOS) Evidence Based Practice Committee, AAOS Guidelines and Technology Oversight Committee, AAOS Council on Research, Quality Assessment, and Technology, and the AAOS Board of Directors.

Preliminary Recommendations

The original work group began work on this guideline by constructing a set of preliminary recommendations. These recommendations specify (what) should be done in (whom), (when), (where), and (how often or how long). They function as questions for the systematic review, not as final recommendations or conclusions. Simulated recommendations are almost always modified on the basis of the results of the systematic review. These recommendations also form the guideline's scope and guide the searches for literature. These *a priori* simulated recommendations are inviolate in that, once specified, they cannot be modified, they must all be addressed by the systematic review, and the relevant review results must be presented in the final guideline. The *a priori* and inviolate nature of the preliminary recommendations combats bias.

Grading the Recommendations

Following data extraction and analyses, each guideline recommendation was assigned a preliminary grade that was based on the total body of evidence available using the system shown in the "Rating Scheme for the Strength of the Recommendations" field.

Each recommendation was constructed using the following language which took into account the final grade of recommendation:

AAOS Guideline Language

Guideline Language	Strength of Recommendation
Strong evidence supports that the practitioner should/should not do X, because…	Strong
Moderate evidence supports that the practitioner could/could not do X, because…	Moderate
Limited evidence supports that the practitioner might/might not do X, because…	Limited
In the absence of reliable evidence, it is the *opinion* of this work group that…	Consensus

Rating Scheme for the Strength of the Recommendations

Strength of Recommendation Descriptions

Strength	Overall Strength of Evidence	Description of Evidence Strength	Strength Visual
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Moderate	Moderate	Evidence from two or more "Moderate" strength studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.	***
Limited	Low Strength Evidence or Conflicting Evidence	Evidence from two or more "Low" strength studies with consistent findings or evidence from a single study for recommending for or against the intervention or diagnostic test or the evidence is insufficient or conflicting and does not allow a recommendation for or against the intervention.	**
Consensus	No Evidence	There is no supporting evidence. In the absence of reliable evidence, the work group is making a recommendation based on their clinical opinion. Consensus recommendations can only be created when not establishing a recommendation could have catastrophic consequences.	*

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Peer Review

The original 2009 draft of the guideline and evidence report were peer reviewed by an expert outside advisory panel that was nominated by the physician work group prior to the development of the guideline (see Appendix VI of the 2015 guideline reissue). In addition, the physician members of the American Academy of Orthopaedic Surgeons (AAOS) Guidelines and Technology Oversight Committee and the Evidence Based Practice Committee provided peer review of the draft document. Peer review was accomplished using a structured peer review form (see Appendix VII in the 2015 guideline reissue). The draft guideline was forwarded to a total of thirty-three reviewers and eleven returned reviews.

The disposition of all non-editorial peer review comments was documented and accompanied this guideline through the public commentary and the following approval process.

Public Commentary

After modifying the draft in response to peer review, the original 2009 guideline was subjected to a thirty-day period of "Public Commentary." Commentators consist of members of the AAOS Board of Directors (BOD), members of the Council on Research, Quality Assessment, and Technology (CORQAT), members of the Board of Councilors (BOC), and members of the Board of Specialty Societies (BOS). Based on these bodies, up to 185 commentators had the opportunity to provide input into the development of this guideline. Of these, 12 returned public comments.

The AAOS Guideline Approval Process

Following peer review, the 2009 clinical practice guideline was approved by the AAOS Guidelines and Technology Oversight Committee, the AAOS Evidence Based Practice Committee, the AAOS CORQAT, and the AAOS BOD.

The 2015 Guideline Reissue was approved by the AAOS Committee on Evidence Based Quality and Value, the AAOS CORQAT and the AAOS BOD. Descriptions of these bodies are provided in Appendix I of the 2015 guideline reissue.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is specifically stated for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

The prolonged loss of mobility and absence from school often associated with the treatment of pediatric diaphyseal femur fractures can lead to adverse physical, social, and emotional consequences for the child as well as the child's family. Treatments that minimize the child's length of immobilization and time out of school are therefore desirable.

Potential Harms

Invasive and operative treatments are associated with known risks (infection, malunion). Contraindications vary widely based on the treatment.

Qualifying Statements

Qualifying Statements

- This Clinical Practice Guideline was developed by an American Academy of Orthopaedic Surgeons (AAOS) physician volunteer Work Group based on a systematic review of the current scientific and clinical information and accepted approaches to treatment and/or diagnosis. This Clinical Practice Guideline is not intended to be a fixed protocol, as some patients may require more or less treatment or different means of diagnosis. Clinical patients may not necessarily be the same as those found in a clinical trial. Patient care and treatment should always be based on a clinician's independent medical judgment, given the individual patient's clinical circumstances.
- Some drugs or medical devices referenced or described in this Clinical Practice Guideline may not have been cleared by the U.S. Food and Drug Administration (FDA) or may have been cleared for a specific use only. The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or device he or she wishes to use in clinical practice.
- The age groups referred to in the specific recommendations are general guides. Obviously, additional factors may affect the physician's

choice of treatment including but not limited to associated injuries the patient may present with as well as the individual's comorbidities, skeletal maturity, and/or specific patient characteristics including obesity. The individual patient's family dynamic will also influence treatment decisions; therefore, treatment decisions made for children who border any age group should be made on the basis of the individual. Decisions will always need to be predicated on guardian and physician communication with discussion of available treatments and procedures applicable to the individual patient. Once the patient's guardian has been informed of available therapies and has discussed these options with his/her child's physician, an informed decision can be made. Clinician input based on experience increases the probability of identifying patients who will benefit from specific treatment options.

Implementation of the Guideline

Description of Implementation Strategy

Guideline Dissemination Plans

Dissemination of the guideline is coordinated by the vice-chair of the physician work group and the American Academy of Orthopaedic Surgeons (AAOS) Evidence Based Quality and Value Coordinator. Dissemination efforts vary by guideline. Publication of most guidelines is announced by an Academy press release and corresponding articles authored by the vice chair and published in the Journal of the American Academy of Orthopaedic Surgeons and AAOS Now.

For selected guidelines, dissemination also includes developing a webinar, developing an Online Module for the Orthopaedic Knowledge Online Web site, producing a Radio Media Tour and producing Media Briefings. The guideline is also distributed at the AAOS Annual Meeting in various venues such as Academy Row and Committee Scientific Exhibits. It will also be distributed at applicable Continuing Medical Education (CME) courses and the AAOS Resource Center.

Other dissemination efforts outside the Academy will include submission of the guideline to the National Guideline Clearinghouse (NGC) and distribution at other medical specialty societies' meetings.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2009 Jun 19 (revised 2015 Jun 12)

Guideline Developer(s)

American Academy of Orthopaedic Surgeons - Medical Specialty Society

Source(s) of Funding

This Clinical Practice Guideline was funded exclusively by the American Academy of Orthopaedic Surgeons (AAOS) who received no funding from outside commercial sources to support the development of this document.

Guideline Committee

American Academy of Orthopaedic Surgeons (AAOS) 2015 Guideline Reissue Work Group

Composition of Group That Authored the Guideline

2015 Guideline Reissue Work Group

Chair, American Academy of Orthopaedic Surgeons (AAOS) Evidence Based Quality and Value Committee: David S. Jevsevar, MD, MBA, Vice Chair, Orthopaedics, Assistant Professor of Orthopaedic Surgery, Dartmouth-Hitchcock Medical Center, Lebanon, NH

Guidelines Oversight Leader, AAOS Evidence Based Quality and Value Committee: Kevin Shea, MD, Intermountain Orthopaedics, Boise, ID

AAOS Staff (2015 Guideline Reissue): William Shaffer, MD, AAOS Medical Director; Deborah Cummins, PhD, Director, Department of Research and Scientific Affairs; Jayson Murray, MA, Manager, Evidence Based Medicine Unit; Ben Brenton, MPH, Research Analyst, Evidence Based Medicine Unit; Anne Woznica, AAOS Medical Librarian; Kaitlyn Sevarino, Evidence Based Quality and Value (EBQV) Coordinator; Erica Linskey, Administrative Assistant, Evidence Based Medicine Unit

2009 Guideline Work Group

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Guidelines Oversight Chair: William C. Watters III, MD, Houston, TX

Guidelines Oversight Vice-chair: Michael J. Goldberg, MD, Children's Hospital and Regional Medical Center

Evidence Based Practice Committee Chair: Michael Warren Keith, MD, Cleveland, OH

Former American Academy of Orthopaedic Surgeons Staff (2009 Guideline): Robert H. Haralson III, MD, MBA; Charles M. Turkelson, PhD; Janet L. Wies, MPH; Patrick Sluka, MPH; Kristin Hitchcock

Financial Disclosures/Conflicts of Interest

All members of the American Academy of Orthopaedic Surgeons (AAOS) work group disclosed their conflicts of interest prior to the development of the recommendations for this guideline. Conflicts of interest are disclosed in writing with the AAOS via a private on-line reporting database and also verbally at the recommendation approval meeting. Members of all AAOS Work Groups are required to disclose their conflicts of interest at the same level and depth of detail as the AAOS Board of Directors.

See Appendix IX in the 2015 guideline reissue for the individual work group members' conflicts of interest from the 2009 guideline.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: American Academy of Orthopaedic Surgeons (AAOS). American Academy of Orthopaedic Surgeons clinical practice guideline on treatment of pediatric diaphyseal femur fractures. Rosemont (IL): American Academy of Orthopaedic Surgeons (AAOS); 2009 Jun 19. 110 p. [49 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the American Academy of Orthopaedic Surgeons (AAOS) Web site .

Availability of Companion Documents

The following is available:

- American Academy of Orthopaedic Surgeons clinical practice guideline on treatment of pediatric diaphyseal femur fractures. Rosemont (IL): American Academy of Orthopaedic Surgeons (AAOS); 2009 Jun 19. 110 p. Available from the American Academy of Orthopaedic Surgeons (AAOS) Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on December 10, 2009. The information was verified by the developer on January 19, 2010. The currency of the guideline was reaffirmed by the developer in 2014 and this summary was updated by ECRI Institute on March 2, 2015. This summary was updated by ECRI Institute on October 12, 2015. The updated information was verified by the guideline developer on November 16, 2015.

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